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STADA

STADA Pharmaceuticals, Inc.
5 Cedar Brook Drive • Cranbury, NJ 08512 • USA
Telephone: 609-409-5999 Fax: 609-409-8315

December 19, 2005

ATTN: Dave Reed

Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
FOOD AND DRUG ADMINISTRATION
Document Control Room
Metro Park North II (HFD-600)
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Fax: 301-443-3839

Re: Docket Number 00P-1466,
ANDA #75-544, Gabapentin Capsules, 100 mg, 300 mg and 400 mg

Dear Dave,

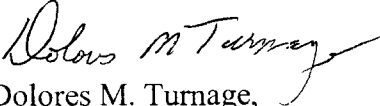
This letter is being written in response to our telephone conversation on Friday, December 16th.

Clonmel Healthcare LTD. was the holder of the above mentioned ANDA as this product had been part of a blanket purchase from ESI Lederle. As STADA has no intention of marketing and distributing this product, it was officially withdrawn in 2004.

I hope this letter satisfies your request. A hard copy of this letter will be posted today, and overnighted to you.

If you have any questions or comments, please feel free to contact me at your convenience at extension 200 or email to dolores.turnage@stadausa.com.

Sincerely,
STADA PHARMACEUTICALS INC.
US AGENT FOR CLONMEL HEALTHCARE


Dolores M. Turnage,
Director, Quality and Regulatory Affairs

Cc: Clonmel, File

00P-1466

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LET 2

Read, David T

From: Dolores Turnage [Dolores.Turnage@stadausa.com]
Sent: Tuesday, January 10, 2006 2:30 PM
To: Read, David T
Subject: Re. Clonmel's ANDA #75-544

Yes, you can include the letter; and you're welcome.
Hope you had a wonderful holiday season and best wishes for a Happy, Healthy, New Year
Regards,
Dolores

>>> "Read, David T" <READD@cder.fda.gov> 1/10/2006 2:13 PM >>>

Ms. Turnage,

Thank you for your letter dated December 19, 2005, regarding the above referenced ANDA. Your letter refers to Docket No. 00P-1466. As we discussed in our conversation of December 16th, do you have any objection if I were to submit your letter for inclusion in that public docket? You need only respond to this e-mail.

Thanks again very much for your prompt attention to this matter.

Dave Read
Regulatory Counsel
Office of Generic Drugs
Center for Drug Evaluation and Research

1/10/2006